

pharmaceutically effective amount of] microparticles sized such that at least 50% of the microparticles are less than 5 μm , the microparticles comprising the at least one antigen entrapped or encapsulated by [a] the biodegradable polymer; and combining a pharmaceutically effective amount of said microparticles with a pharmaceutically acceptable carrier to provide said vaccine formulation for oral administration.

Claim 2, line 1, change "vaccine formulation" to --method--.

3. (Amended) The [vaccine formulation] method of Claim 1, wherein the biodegradable polymer comprises a copolymer of lactic acid or an enantiomer of lactic acid with [and] glycolic acid or [enantiomers thereof] an enantiomer of glycolic acid.

Claim 5, line 1, change "vaccine formulation" to --method--.

Claim 6, line 1, change "vaccine formulation" to --method--.

7. (Amended) A method for producing a vaccine formulation for oral administration, said method comprising:

coacervating at least one antigen with a biodegradable polymer to provide [a pharmaceutically acceptable carrier and a pharmaceutically effective amount of] nanoparticles sized such that at least 50% of the nanoparticles are less than 600nm, the nanoparticles comprising the at least one

A3

antigen entrapped or encapsulated by [a] the
biodegradable polymer; and
combining a pharmaceutically effective amount of said
nanoparticles with a pharmaceutically acceptable carrier
to provide said vaccine formulation for oral
administration.

Claim 8, line 1, change "vaccine formulation" to --method--.

A4

9. The [vaccine formulation] method of Claim 7, wherein the
biodegradable polymer comprises a copolymer of lactic acid or an
enantiomer of lactic acid with [and] glycolic acid or [enantiomers
thereof] an enantiomer of glycolic acid.

Claim 11, line 1, change "vaccine formulation" to --method--.

Claim 12, line 1, change "vaccine formulation" to --method--.

A5

13. (Amended) A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of microparticles sized such that at least 50% of the microparticles are less than 5 μm , the microparticles comprising at least one *B. pertussis* antigen selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA) and pertactin, entrapped or encapsulated by a biodegradable polymer.

A6

15. (Amended) The method of Claim 13, wherein the biodegradable polymer comprises a copolymer of lactic acid or an

~~enantiomer of lactic acid with [and] glycolic acid or [and enantiomers thereof] or an enantiomer of glycolic acid~~ and wherein the microparticles are formed using a solvent evaporation method.

a.6
16. (Amended) The method of Claim 13, wherein the at least one *B. pertussis* antigen [is selected from the group consisting of] comprises inactivated pertussis toxin (PTd) [,] and filamentous hemagglutinin (FHA) [, pertactin and fimbriae and combinations thereof].

17. (Amended) A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of nanoparticles sized such that at least 50% of the nanoparticles are less than 600nm, the nanoparticles comprising at least one *B. pertussis* antigen selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA) and pertactin, entrapped or encapsulated by a biodegradable polymer.

a.7
19. (Amended) The method of Claim 17, wherein the biodegradable polymer comprises a copolymer of lactic acid or an enantiomer of lactic acid with [and] glycolic acid or [enantiomers thereof] an enantiomer of glycolic acid and wherein the nanoparticles are formed using a coacervation method.

20. (Amended) The method of Claim 17, wherein the at least one *B. pertussis* antigen [is selected from the group consisting of]